FY2010 Appropriations Request Form

Office of Congresswoman Jackie Speier
211 Cannon House Office Building
Washington, D.C. 20515
Phone: 202/225-3531
Fax: 202/226-4183
Website: www.speier.house.gov

Individuals/Organizations must respond to all questions on the form. Incomplete proposals will not be considered.

All requests will be evaluated before the 12th Congressional District's Citizens Oversight Panel. Appointments to appear before the panel must be made through Cookab Hashemi, chief of staff, at 202/225-3531 or Cookab.Hashemi@mail.house.gov. The panel will convene on the following days; Saturday, March 7, Friday, March 13 and Friday, March 20, 2009. All proposals must be submitted by March 2, 2009.

Date Submitted: March 2, 2009

Project Name: Myeloid Progenitor for Acute Radiation Syndrome

Individual/Organization: *(Is the grantee located in the 12th Congressional District?)*

Cellerant Therapeutics, Inc. – located in San Carlos, which is in the 12th congressional district

Amount Requested (*if requesting report language, please attach*.): $3,000,000

Appropriations Bill/Account/Relevant Authorization law/bill/status (*e.g., "Public Law 107-111"; "FY2008 DOD Authorization", "Currently pursuing authorization through Agriculture Committee", "Safe Drinking Water Act" or "Hatch Act")*:

FY2010 DOD Appropriations Bill
RDT&E Defense-Wide
BA4 – Advanced Component Development and Prototype
Chemical and Biological Defense Program
0603884BP - CHEMICAL/BIOLOGICAL DEFENSE (ATD)
Line No: 075

DOD has authority to fund these types of research efforts. This specific project has not been authorized, however, this area of research has been identified as a Department of Defense research priority.

Local Contact (*Please provide full contact information, including any relevant phone extensions, and indicate if there is a separate D.C. contact*.):

Ram Mandalam, President and CEO
Cellerant Therapeutics, Inc.
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San Carlos, CA 94070
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Organization's Main Activities. (*Please limit your response to 250 words and indicate whether it is a public, private, non-profit or private for-profit entity*.)

Cellerant Therapeutics is a private, for-profit, biotechnology company with a portfolio of products based on the regulation of the hematopoietic (blood-forming) system. The company focuses on curative therapies for seriously ill patients. Cellerant is developing a novel, cell-based medicine (Myeloid Progenitors / CLT-008) as a treatment for chemotherapy and radiation-induced neutropenia as well as for Acute Radiation Syndrome. And we are applying our expertise in hematopoietic ontogeny to identify novel drug targets and therapeutic antibodies aimed at cancer stem cells.

Please show main items in the project and total cost in a simplified chart form. (*Please include the amount of any Federal/State/Local/Private funds, including any in-kind resources.*)

The funds, as outlined below, will be used for hiring additional skilled personnel, manufacturing of CLT-008 for clinical trials and conducting clinical trials.

Personnel	$1,000,000
Biologics & Contract Services for manufacturing	$1,350,000
Supplies & Testing	$200,000
Costs for clinical trials: contract services, patients' care	$450,000
Total Direct Costs	$3,000,000

Project Description, including a timeline, goals, expected outcomes and specific uses of Federal Funds. (*Your response must focus on the requested funds rather than the organization's mission and general activities*. *Please limit your response to 250 – 500 words.)*

DOD funding would accelerate demonstration of safety and efficacy of CLT-008 in clinical trials to treat military troops in the field and U.S. civilian victims of a nuclear terror incident. Funds are not available from private investors to meet the national interest. In December of 2008, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, concluded in its report entitled, World at Risk, "that unless the world community acts decisively and with great urgency, it is more likely than not that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013." If an attack were to occur, our nation is extremely vulnerable and unprepared to treat victims of such an event. Our forward deployed military personnel are vulnerable as are our citizens at home. There is no medical treatment currently available for anyone exposed to enough radiation to cause Acute Radiation Syndrome (ARS). This condition leads to lethal infections and internal bleeding – the most dangerous side effects resulting from a massive release of radiation that might be caused by a terrorist attack on a nuclear power plant or the use of a nuclear weapon. CLT-008 is unique in that it can be administered 4-6 days after exposure, making its use practical for mass casualty situations and for field war fighters.

Cellerant is requesting federal funding specifically to support clinical trials which will treat a sufficient number of people to provide the FDA with a basis for accelerated approval under the normal drug review processes or for the so-called Animal Rule Approval for Biodefense products. The funds will be used to conduct clinical trials in chemotherapy induced neutropenia patients. Department of Defense funding will accelerate the clinical development program for CLT-008, providing a near term treatment option for our troops, and a long-term benefit to the U.S. civilian population by reducing future acquisition costs for the Strategic National Stockpile.

This funding is essential for ensuring timely development of this medical countermeasure and will permit the company to complete all studies necessary for obtaining FDA approval of a final product 2-3 years sooner than if the company is required to seek alternative funding from other sources, public or private. If adequate funding is provided and our study results achieve anticipated results, we would expect to have an approved product within 4-5 years.

How will this earmark serve to expand the capacity of your organization and how will your organization sustain this work beyond the federal funding? (*Your response must focus on the impact of the requested funds rather than the organization's long-term goals*.)

Funds obtained from this request will be used to hire additional personnel, including two manufacturing and quality systems personnel, a clinical operations manager, and one clinical research associate. Future funding sources for these additional staff positions will come from additional federal grants and funds raised from outside private sources.

What is the local significance of this project?

This project will lead to increased employment at our company and the related companies with whom we do business. We have collaborated with several researchers at Stanford University and these collaborations might be expanded as a result of this project. This project has national significance as well, as it may represent the only available treatment to people if we have some type of nuclear incident, such as an attack on a nuclear power plant, or possibly detonation of a nuclear device either in the U.S. or in foreign countries in which our military troops are forward deployed.

How many residents of the 12th CD will benefit from this project? *(i.e. jobs created, services rendered to, how many people, etc.)*

Initially, up to four jobs would be created with funds for this project. More broadly, all residents of the 12th CD will benefit if our work results in an FDA-approved product to treat Acute Radiation Syndrome. Moreover, this work may also permit the company to advance new products or obtain approval for additional, non-biodefense indications. Cancer patients might also be a significant beneficiary of our work.

List any other organizations or state/local elected officials who have expressed support for the project in writing. (*Please submit copies of support letters along with the proposal*.)

N/A

Does the organization have any other funding requests for this project? (*Federal, State, Local or private pending*?)

We do not currently have other funding requests specifically for this project. We have received some funding from the Department of Defense for the initial stages of this project. The company is also currently engaged in a collaboration with the Armed Forces Radiobiology Research Institute (AFRRI) for evaluation of CLT-

008 as a nuclear countermeasure in their radiation models. Preliminary results from studies performed under this collaboration have validated Cellerant's results. Cellerant has also been awarded peer-reviewed grants from the National Institutes of Health (NIAID) and a contract from BARDA. BARDA's contract will fund the critical large-animal studies required for approval of the product for ARS and a part of initial Phase 1 clinical trial. The requested funds will accelerate human clinical trials to demonstrate the safety of CLT-008 in humans.

Has the organization previously received Federal funds for this project? (*Please list any funds received [by fiscal year] and briefly describe how those funds were spent*.)

Appropriations History:

DOD, RDT&E, FY 2009: House: $0	Senate: $0	Conference:	$0
DOD, RDT&E, FY 2008: House: $3 million	Senate: $0	Conference:	$2.4 million
DOD, RDT&E, FY 2007: House: $1 million	Senate: $0	Conference:	$1 million

Please attach a list of your organization's staff and board members (*if any*).

Management
Ram Mandalam, *President & CEO*
James Maluta, *VP of Product Development*
Elisa Brunette, *Director of Technology Transfer*
Steve Decker, *Financial Controller*

Board of Directors
Richard Chyette, *Corporate Counsel/Secretary, Quicken Loans Inc.; Advisor, Camelot Ventures LLC*
Rick Rathmann, *Chairman*
Ram Mandalam, *President & CEO*
Steve Greenberg, *Managing Director, Allen & Company LLC*
Antoun Nabhan, *Principal, Sagamore Bioventures*
George B. Rathmann, *Chariman Emeritus*

Please attach any additional relevant materials.